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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,990	03/12/2007	Ettore Tallia	1011-784	3630
47888	7590	03/16/2010	EXAMINER	
HEDMAN & COSTIGAN P.C. 1185 AVENUE OF THE AMERICAS NEW YORK, NY 10036			ROBERTS, LEZAH	
			ART UNIT	PAPER NUMBER
			1612	
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			03/16/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/562,990	TALLIA, ETTORE	
	<b>Examiner</b>	<b>Art Unit</b>	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 13 October 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 11-14 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 11-14 is/are rejected.  
 7) Claim(s) 11 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
     1. Certified copies of the priority documents have been received.  
     2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
     3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### ***Status of claims***

The Amendment filed on 10/13/2009 has been entered. Claims 1-10 have been cancelled. New claims 11-14 have been added, introducing no new matter. Currently, claims 11-14 are under consideration.

### ***Previous Rejections***

Applicants' arguments, filed on 10/19/2009, have been fully considered. Rejections not reiterated from previous office actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

### ***Claims***

#### **Claim Objections**

Claim 11 is objected to because of the following informalities:

- 1) The word "stable" in claim 11 is misspelled.

2) An "A" should be inserted in from the "Mouthwash anti-bacteric composition" to read "A mouthwash anti-bacteric composition".

Appropriate correction is required.

### **Claim Rejections - 35 USC § 112 - Indefiniteness**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 14 recites "a composition.... adapted to form stable emulsions". It is not clear how the compositions are "adapted" to form said stable emulsions.

### **Claim Rejections - 35 USC § 103 – Obviousness**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright (US 5,618,840) in view of Pianotti (EP 0244363) and Kunz et al. (US 2002/0169138).

Wright teaches antibacterial oil-in-water emulsions (title). The emulsions are stable when heated or exposed to significant levels of acid and base (column 2, lines 56-57), encompassing instant claim 14. The emulsions can be used in pharmaceutical preparations, made up of an antibacterial emulsion and a pharmaceutically acceptable carrier (column 2, lines 58-65). Said preparations can be applied to oral surfaces, for example, as a mouthwash (column 3, lines 1-5). Oils useful in forming oily discontinuous phase of said emulsions include vegetable oils, such as soybean oil, canola oil, glycerol esters and mixtures thereof (column 2, lines 19-22). Said oily phase includes cetylpyridinium chloride (antiseptic substance) (column 2, lines 29-32). The amounts of oil phase to water phase range from 1:4 to 1:2 on a volume to volume basis (column 4, lines 35-38). This encompasses instant claim 11.

Wright does not disclose the anti-bacteric substances incorporated into the aqueous phase, however, Wright mentions that they are well known in the art (column 5, lines 21-22). The reference is also silent about the visual appearance of the emulsions and the oils include aliphatic hydrocarbons, esters, alcohols and ethers.

Pianotti teaches an oral preparation in the form of mouthwash or rinse (Page 3, line 24). The vehicle (e.g. pharmaceutically acceptable carrier, as described by the primary reference) is a water-alcohol mixture, present in the mouthrinse in an amount from 70 to 99.9% (page 3, lines 27-28), which is within the range for the aqueous phase disclosed in the instant claim 11. Water soluble compounds that comprise said vehicle are inorganic fluoride salts (page 3, lines 53-54), saccharin (page 4, line 19), xylitol (page 4, line 16), as well as colorants (page 4, line 11), encompassing instant claims 12 and 13. Example 4 on pages 7 and 8 demonstrates a mouthrinse comprising ethanol, encompassing instant claim 13. Essential oils, also flavor oils, include thymol, eucalyptol, and menthol encompass aromatic oils. The reference differs from the instant claims insofar as it does not disclose the compositions as emulsions and only discloses the aromatic oils as a component encompassed by the oil phase.

Kunz et al. disclose delivery vehicles for bioactive agents and is used to disclose oils used in oil-in-water emulsions. The compositions may be delivered orally (paragraph 0132). The vehicles include emulsions such as oil-in-water emulsions (paragraph 0116). The oils include vegetable oils, mineral oils, aromatic hydrocarbons, oils having animal origins, aliphatic hydrocarbons, aliphatic alcohols, triglycerides, and hydrocarbons comprising esters and ethers (paragraphs 0045-0054). The oils may also

be used in mixtures (paragraph 0109). When the emulsions are diluted with water, they become cloudy (paragraph 0113).

The reference differs from the instant claims insofar as it does not disclose the phase in which the active is dissolved or water soluble actives.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have used the mouthwash composition comprising a water-alcohol mixture, fluoride, saccharine and xylitol as the aqueous pharmaceutical carrier of Wright and oils such as mineral oils, aromatic oils, aliphatic hydrocarbons, triglycerides, hydrocarbons comprising esters and ethers in mixtures in the oil phase in addition to those disclosed by Wright when formulating an oil-in-water mouthwash motivated by the desire to use a vehicle known in the art as suitable for mouthwashes, as disclosed by Pianotti, and oils suitable for use in the oil phase of oil-in-water emulsions as disclosed by Kunz et al. and supported by MPEP 2144.07.

As far as visual appearance is concerned, one skilled in the art would reasonably expect a formulation comprising oil and water phases combined in amounts described by the primary reference, encompassing those amounts recited by the instant claims, to be opaque. The disclosure of Kunz et al. further supports this reasoning by disclosing the addition of water causes the concentrated oil and water emulsions to become cloudy.

Claims 11-14 are rejected.

Claim 11 is objected.

No claims allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612